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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PANARO, NICHOLAS J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/653,321	LAWTON, ROBERT L.	
	Examiner	Art Unit	
	Nicholas J. Panaro	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 44 are drawn to a method of detecting a compound of interest in a sample classified in class 435, sub class 6, for example.

II. Claims 45-46 are drawn to a kit for detecting a compound of interest in a sample classified in class 422, subclass 61, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of Group I could be used to produce multiple copies of a nucleic acid.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Thomas Foster on October 22, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-44. Affirmation of this election must be made by applicant in replying to this Office action. Claim 45 and 46 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as exemplified by their different classification, restriction for examination purposes as indicated is proper. Further, a search for the inventions of both groups would not be co-extensive because a search indicating the process is novel or nonobvious would not extend to a holding that the product itself is novel or nonobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The application contains two claims numbered 7, two claims numbered 38, and two claims numbered 39. The second Claim 7 has been renumbered as Claim 8. Misnumbered Claims 8-37 and all references and dependencies thereof have been renumbered Claims 9-38. The first misnumbered Claim 38 and all references and dependencies thereof have been renumbered as Claim 39. The first misnumbered Claim 39 and all references and dependencies thereof have been renumbered as Claim 40. The second misnumbered Claim 38 and all references and dependencies thereof have been renumbered as Claim 41. The second misnumbered Claim 39 and all references and dependencies thereof have been renumbered as Claim 42. Misnumbered Claims 40-43 and all references and dependencies thereof have been renumbered as Claims 43-46.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-22 and 41-44 are indefinite in Claim1, step (d) for "said mixture" because the term lacks antecedent basis. It is suggested that "complex" be substituted for "mixture".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-15, 19-20, 23-37 and 41-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Blackburn et al (U.S. Patent 6,686,150, filed July 20, 2000).

Regarding Claim 1, Blackburn et al teach a method for detecting a compound of interest in a sample comprising the steps of (a) providing a binding construct (primary probe #1) comprising a recognition portion (first probe sequence #10) which recognizes and binds said compound of interest; (b) mixing said binding construct with said sample to form construct-compound complexes (hybridization complex 6); (c) providing one or more surfaces (bead 200), wherein said surface bears one or more accessible binding targets capable of recognizing and binding to said recognition portion of said binding construct (212, separation sequence); (d) introducing said one or more surfaces to said mixture of said binding construct and said sample in order for said one or more surfaces to form construct-surface complexes with any unbound binding constructs (cleaved probes remain are are bound to electrode for detection); (e) separating said construct-surface complexes from said mixture leaving behind said construct-compound complexes; (f) detecting the presence or absence of said nucleic acid portion of said binding construct (Column 11, lines 24-62; Figure 33).

Regarding Claim 2, Blackburn et al further teach wherein said one or more surfaces is selected from the group consisting of: particles, powders, beads, planar structures, non-planar structures, a tube, a well, non-porous films, non-porous membranes, porous films, porous membranes, fibers, fillers, meshes, grids, filters, matrices, gels, and combinations thereof (i.e., beads, Column 31, lines 54-60).

Regarding Claim 3, Blackburn et al teach wherein said one or more surfaces are particles (i.e., beads, Column 31, lines 54-60).

Regarding Claim 4, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads (Column 31, lines 54-60).

Regarding Claim 5, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads) wherein said magnetic particles are separated from the mixture by means of a magnet (Column 31, lines 54-60).

Regarding Claim 6, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 7, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 8, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 3, lines 34-53).

Regarding Claim 9, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 10, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 11, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 3, lines 34-53).

Regarding Claim 12, Blackburn et al further teach wherein said recognition portion comprises a receptor (i.e., suitable affinity moieties, Column 32, lines 6-23).

Regarding Claim 13, Blackburn et al further teach wherein said recognition portion comprises an antigen (i.e., a hapten, Column 32, lines 14-22).

Regarding Claim 14, Blackburn et al further teach wherein said recognition portion comprises an antibody (Column 32, lines 14-22).

Regarding Claim 15, the claim language states "said recognition portion comprises a single chain antibody variable region". The open claim language "comprising" encompasses additional components (e.g., a complete antibody). Blackburn et al teach wherein said recognition portion comprises an antibody (Column 32, lines 14-22). Because every antibody consists of two heavy chains and two light chains and each chain possesses a variable region, Blackburn et al further teach wherein said recognition portion comprises a single chain antibody variable region (Column 32, lines 14-22).

Regarding Claim 19, Blackburn et al further teach wherein said nucleic acid portion comprises DNA (Column 13, lines 18-25).

Regarding Claim 20, Blackburn et al further teach wherein said nucleic acid portion comprises RNA (Column 13, lines 18-25).

Regarding Claim 23, Blackburn et al teach a method for detecting a compound of interest in a sample comprising the steps of (a) providing a binding construct (primary probe #1) comprising a recognition portion (first probe sequence #10) which recognizes and binds said compound of interest; (b) mixing said binding construct with said sample to form construct-compound complexes (hybridization

complex 6); (c) providing one or more surfaces (bead 200), wherein said surface bears one or more accessible binding targets capable of recognizing and binding to said recognition portion of said binding construct (212, separation sequence); (d) introducing said one or more surfaces to said mixture of said binding construct and said sample in order for said one or more surfaces to form construct-surface complexes with any unbound binding constructs; (e) separating said construct-surface complexes from said mixture leaving behind said construct-compound complexes (cleaved probes remain and are bound to electrode for detection); (f) detecting the presence or absence of said nucleic acid portion of said binding construct (Column 11, lines 24-62; Figure 33).

Regarding Claim 24, Blackburn et al further teach wherein said one or more surfaces is selected from the group consisting of: particles, powders, beads, planar structures, non-planar structures, a tube, a well, non-porous films, non-porous membranes, porous films, porous membranes, fibers, fillers, meshes, grids, filters, matrices, gels, and combinations thereof (i.e., beads, Column 31, lines 54-60).

Regarding Claim 25, Blackburn et al teach wherein said one or more surfaces are particles (i.e., beads, Column 31, lines 54-60).

Regarding Claim 26, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads (Column 31, lines 54-60).

Regarding Claim 27, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads) wherein said magnetic particles are separated from the mixture by means of a magnet (Column 31, lines 54-60).

Regarding Claim 28, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 29, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 30, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 3, lines 34-53).

Regarding Claim 31, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 32, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 3, lines 34-53).

Regarding Claim 33, Blackburn et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 3, lines 34-53).

Regarding Claim 34, Blackburn et al further teach wherein said recognition portion comprises a receptor (i.e., suitable affinity moieties, Column 32, lines 6-23).

Regarding Claim 35, Blackburn et al further teach wherein said recognition portion comprises an antigen (Column 37, lines 1-6).

Regarding Claim 36, Blackburn et al further teach wherein said recognition portion comprises an antibody (Column 32, lines 14-22).

Regarding Claim 37, the claim language states "said recognition portion comprises a single chain antibody variable region". The open claim language "comprising" encompasses additional components (e.g., a complete antibody). Blackburn et al teach wherein said recognition portion comprises an antibody (Column 32, lines 14-22). Because every antibody consists of two heavy chains and two light chains and each chain possesses a variable region, Blackburn et al further teach wherein said recognition portion comprises a single chain antibody variable region (Column 32, lines 14-22).

Regarding Claim 41, Blackburn et al further teach wherein said nucleic acid portion comprises DNA (Column 13, lines 18-25).

Regarding Claim 42, Blackburn et al further teach wherein said nucleic acid portion comprises RNA (Column 13, lines 18-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baez et al (U.S. Patent 6,511,809, issued January 28, 2003) in view of Blackburn et al (U.S. Patent 6,686,150, filed July 20, 2000).

Regarding Claim 1, Baez et al teach a method for detecting a compound of interest in a sample comprising the steps of (a) providing a binding construct comprising a recognition portion which recognizes and binds (i.e., antibody and nucleic acid fragment) said compound of interest (Column 3, lines 34-41); (b) mixing said binding construct with said sample to form construct-compound complexes (Column 3, lines 54-59); (c) providing one or more surfaces, wherein said surface bears one or more accessible binding targets capable of recognizing and binding to said recognition portion of said binding construct (Column 10, Lines 53-56 and Column 11, lines 16-18); (f) detecting the presence or absence of said nucleic acid portion of said binding construct (Column 3, lines 59-64). Baez et al does not teach (d) introducing said one or more surfaces to said mixture of said binding construct and said sample in order for said one or more surfaces to form construct-surface complexes with any unbound binding constructs nor does it teach (e) separating said construct-surface complexes from said mixture leaving behind said construct-compound complexes.

Blackburn et al teach a similar method in which nucleic acid detection is achieved via the binding and amplification of said nucleic acids. Blackburn et al teach (d) introducing said one or more surfaces to said mixture of said binding construct and said sample in order for said one or more surfaces to form construct-surface complexes with any unbound binding constructs and (e) separating said construct-surface complexes from said mixture leaving behind said construct-compound complexes (Column 11, lines 24-62) whereby the removal of the unbound constructs decreases false positive signals (Column 31, Lines 48-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the separation complex of Blackburn to the method of Baez et al to remove unbound binding constructs from said mixture. One of ordinary skill would have been motivated to do so for the advantages of the removal of the unbound constructs decreases false positive signals (Column 31, Lines 48-60).

Regarding Claim 2, Blackburn et al teach wherein said one or more surfaces are is selected from the group consisting of: particles, powders, beads, planar structures, non-planar structures, a tube, a well,

non-porous films, non-porous membranes, porous films, porous membranes, fibers, fillers, meshes, grids, filters, matrices, gels, and combinations thereof (i.e., beads, Column 35, lines 50-55).

Regarding Claim 3, Blackburn et al teach wherein said one or more surfaces are particles (i.e., beads, Column 35, lines 50-55).

Regarding Claim 4, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads (Column 31, lines 54-60).

Regarding Claim 5, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads) wherein said magnetic particles are separated from the mixture by means of a magnet (Column 31, lines 54-60).

Regarding Claim 6, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 7, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 8, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 5, lines 26-29).

Regarding Claim 9, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 10, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 11, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 5, lines 26-29).

Regarding Claim 12, Baez et al further teach wherein said recognition portion comprises a receptor (Column 7, lines 54-57).

Regarding Claim 13, Baez et al further teach wherein said recognition portion comprises an antigen (Column 7, lines 54-57).

Regarding Claim 14, Baez et al further teach wherein said recognition portion comprises an antibody (Column 7, lines 54-57).

Regarding Claim 15, the claim language states "said recognition portion comprises a single chain antibody variable region". The open claim language "comprising" encompasses additional components (e.g., a complete antibody). Baez et al teach wherein said recognition portion comprises an antibody (Column 7, lines 54-57). Because every antibody consists of two heavy chains and two light chains and each chain possesses a variable region, Baez et al further teach wherein said recognition portion comprises a single chain antibody variable region (Column 7, lines 54-57).

Regarding Claim 16, Baez et al further teach wherein said recognition portion comprises an antibody (Column 7, lines 54-57). Baez et al further teach a Fab fragment as a member of an antigen/antibody binding pair (Column 15, lines16-34).

Regarding Claim 17, Baez et al further teach wherein said binding pairs (i.e., recognition portion such as a Fab fragment and nucleic acid portion) form covalent bonds via sulfhydyrl groups (Column 7, lines 54-57).

Regarding Claim 18, Baez et al further teach wherein said compound of interest comprises an antibody fragment, said recognition portion of said binding construct comprises an antigen that is recognized by said compound of interest, and said accessible binding targets comprise an antibody or antibody fragment that is capable of recognizing and binding to said recognition portion of said binding construct (Column 11, line 10 – Column 12, line 9; Figures 1 and 2).

Regarding Claim 19, Baez et al further teach wherein said nucleic acid portion comprises DNA (Column 5, lines 35-37).

Regarding Claim 20, Baez et al further teach wherein said nucleic acid portion comprises RNA (Column 5, lines 35-37).

Regarding Claim 21, Baez et al further teach wherein said nucleic acid portion comprises a nucleic sequence that does not include a sequence that is expected to be found in the sample (Column 7, lines 41-53).

Regarding Claim 22, Baez et al further teach providing two or more different types of binding constructs, wherein each of said two or more different binding constructs has a different recognition portion and a different nucleic acid portion (Column 15, line 66 – Column 16, line 3).

Regarding Claim 23, Baez et al teach a method for detecting a compound of interest in a sample comprising the steps of (a) providing a sample suspected of containing said compound of interest (Column 27, lines 28-41), (b) providing a binding construct comprising: (i) a recognition portion capable of binding said compound of interest, and (ii) a nucleic acid portion; (i.e., antibody and nucleic acid fragment, Column 3, lines 34-41); (c) contacting said sample with said binding construct for a period of time sufficient to permit said recognition portion to bind said compound of interest present in said sample, thereby forming construct-compound complexes in solution (Column 3, lines 54-59); (d) providing one or more surfaces, wherein said one or more surfaces bear one or more accessible binding target capable of binding to said recognition portion (Column 10, Lines 53-56 and Column 11, lines 16-18); (g) detecting the presence or absence of said nucleic acid portion of said binding construct in said solution, wherein said separation of said construct-surface complexes from said solution results in a separation of substantially all binding constructs not bound to a compound of interest (Blackburn et al, Column 35, lines 50-55) and in an increased sensitivity of detection of said compound of interest (Column 12, lines 43-48), and wherein the presence of said nucleic acid portion of said binding construct indicates the presence of said compound of interest in said sample (Column 3, lines 59-64). Baez et al does not teach (e) contacting said one or more surfaces with said solution for a period of time sufficient for said one or more accessible binding target to bind said recognition portion of any binding construct not bound to said compound of interest, thereby forming construct-surface complexes nor does it teach (f) separating said construct-surface complexes from said solution, leaving said construct-compound complexes in said solution.

Blackburn et al teach a similar method in which nucleic acid detection is achieved via the binding and amplification of said nucleic acids. Blackburn et al teach (d) introducing said one or more surfaces to said mixture of said binding construct and said sample in order for said one or more surfaces to form

construct-surface complexes with any unbound binding constructs and (e) separating said construct-surface complexes from said mixture leaving behind said construct-compound complexes (Column 11, Lines 24-62) whereby the removal of the unbound constructs decreases false positive signals (column 31, Lines 48-60)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the separation complex of Blackburn to the method of Baez et al to remove unbound binding constructs from said mixture. One of ordinary skill would have been motivated to do so for the advantages of the removal of the unbound constructs decreases false positive signals (Column 31, Lines 48-60).

Regarding Claim 24, Blackburn et al teach wherein said one or more surfaces are is selected from the group consisting of: particles, powders, beads, planar structures, non-planar structures, a tube, a well, non-porous films, non-porous membranes, porous films, porous membranes, fibers, fillers, meshes, grids, filters, matrices, gels, and combinations thereof (i.e., beads, Column 35, lines 50-55).

Regarding Claim 25, Blackburn et al teach wherein said one or more surfaces are particles (i.e., beads, Column 35, lines 50-55).

Regarding Claim 26, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads (Column 31, lines 54-60).

Regarding Claim 27, Blackburn et al further teach the addition of magnetic particles (i.e., magnetic beads) wherein said magnetic particles are separated from the mixture by means of a magnet (Column 31, lines 54-60).

Regarding Claim 28, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 29, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 30, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 5, lines 26-29).

Regarding Claim 31, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 32, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion (Column 5, lines 26-29).

Regarding Claim 33, Baez et al further teach said detection of the presence or absence of said nucleic acid portion of said binding construct comprises amplification of said nucleic acid portion wherein said amplification comprises a polymerase chain reaction (Column 5, lines 26-29).

Regarding Claim 34, Baez et al further teach wherein said recognition portion comprises a receptor (Column 7, lines 54-57).

Regarding Claim 35, Baez et al further teach wherein said recognition portion comprises an antigen (Column 7, lines 54-57).

Regarding Claim 36, Baez et al further teach wherein said recognition portion comprises an antibody (Column 7, lines 54-57).

Regarding Claim 37, the claim language states "said recognition portion comprises a single chain antibody variable region". The open claim language "comprising" encompasses additional components (e.g., a complete antibody). Baez et al teach wherein said recognition portion comprises an antibody (Column 7, lines 54-57). Because every antibody consists of two heavy chains and two light chains and each chain possesses a variable region, Baez et al further teach wherein said recognition portion comprises a single chain antibody variable region (Column 7, lines 54-57).

Regarding Claim 38, Baez et al further teach wherein said recognition portion comprises an antibody (Column 7, lines 54-57). Baez et al further teach a Fab fragment as a member of an antigen/antibody binding pair (Column 15, lines16-34).

Regarding Claim 39, Baez et al further teach wherein said binding pairs (i.e., recognition portion such as a Fab fragment and nucleic acid portion) form covalent bonds via sulfhydyrl groups (Column 7, lines 54-57).

Regarding Claim 40, Baez et al further teach wherein said compound of interest comprises an antibody fragment, said recognition portion of said binding construct comprises an antigen that is recognized by said compound of interest, and said accessible binding targets comprise an antibody or antibody fragment that is capable of recognizing and binding to said recognition portion of said binding construct (Column 11, line 10 – Column 12, line 9; Figures 1 and 2).

Regarding Claim 41, Baez et al further teach wherein said nucleic acid portion comprises DNA (Column 5, lines 35-37).

Regarding Claim 42, Baez et al further teach wherein said nucleic acid portion comprises DNA (Column 5, lines 35-37).

Regarding Claim 43, Baez et al further teach wherein said nucleic acid portion comprises a nucleic sequence that does not include a sequence that is expected to be found in the sample (Column 7, lines 41-53).

Regarding Claim 44, Baez et al further teach providing two or more different types of binding constructs, wherein each of said two or more different binding constructs has a different recognition portion and a different nucleic acid portion (Column 15, line 66 – Column 16, line 3).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas J. Panaro whose telephone number is (571) 272-0778. The examiner can normally be reached on Monday - Friday 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NJP

BJ FORMAN, PH.D.
PRIMARY EXAMINER